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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,735	11/19/2001	Avi J. Ashkenazi	P2730P1C61	2513

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,735	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *119-126,129-132 and 134-138* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *124-126, 129-131, 135-138* is/are allowed.

6)☒ Claim(s) *119-123,132 and 134* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/6/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. The Amendment dated 8/6/04 has been entered into the record.

B. Claims 119-138 were pending in this Office Action. In the Amendment dated 8/6/04, Applicants canceled claims 127, 128 and 133. Therefore, claims 119-126, 129-132 and 134-138 are pending and are the subject of this Office Action.

C. The Information Disclosure Statement dated 8/10/04 has been entered into the record. All references have been considered.

D. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Priority

A. After review of Applicants' arguments as well as the specification, the Examiner agrees that the chondrocyte proliferation assay is a specific, substantial and well-established utility. Therefore, the present invention possesses utility under 35 USC 101 and is enabled under 35 USC 112, first paragraph. Therefore, the present invention receives priority to PCT/US00/08439, filed March 30, 2000.

3. Specification

A. Though no objection was made to the specification regarding hyperlinks, it is noted that Applicants have amended the specification to remove any hyperlinks.

B. The objection to the specification regarding the title has been withdrawn in view of Applicants' amendment to the title to recite "Nucleic Acids Encoding PRO844 Polypeptides."

C. The specification remains objected to since the status of application 09/380,137 has not been updated to "now abandoned." Applicants did not address this issue.

4. Claim Objections

A. The objection to claims 119-126, 129-132 and 134-138 has been withdrawn in view of Applicants' amendment to the claims to replace the phrase "shown in Figure 239 (SEQ ID NO:344)" with "of SEQ ID NO:344."

5. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. The rejection of claims 119-126, 129-132 and 134-138 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendment to the specification (1) stating the current ATCC address; and (2) incorporating the requisite assurances that "all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the pertinent U.S. patent." (also see original page 566 of the specification).

B. Claims 119-123, 132 and 134 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action mailed 5/6/04. Applicants argue that the instantly pending claims have been amended to include a functional recitation "wherein the polypeptide encoded by said nucleic acid induces chondrocyte proliferation" and that they have removed references to "extracellular domains."

These arguments have been considered, but are not deemed persuasive. Page 4 of the Office Action mailed 5/6/04 states that "there are no working examples of polynucleotides or polypeptides less than 100% identical to SEQ ID N0:344 or 345." Though Applicants have added a functional limitation, "the claims are [still] broad because they do not require the claimed polypeptide to be identical to the disclosed sequence."

Applicants have only enabled the use of polynucleotides (SEQ ID NO:344) of the full-length protein of SEQ ID NO:345 (and that encoded by ATCC No. 209976) to induce chondrocyte proliferation. The only disclosure regarding PRO844 (SEQ ID NO:344 and 345) can be found on pages 215 and 362 of the specification. Nowhere in the specification do Applicants disclose working examples of polypeptides which are less than the full-length of SEQ ID NO:345, or of their encoding polynucleotides, including molecules which hybridize to SEQ ID NO:344 and which hybridize to that encoding SEQ ID NO:345, including those at least 10 nucleotides in length. Polypeptides which are less than the full-length of SEQ ID NO:345 would have one or more amino acid substitutions, deletions, insertions and/or additions to the polypeptide of SEQ ID NO:345. Similarly, polynucleotides other than, or which are less than, the full-length of SEQ ID NO:344 would have one or more nucleic acid substitutions, deletions, insertions and/or

additions to the polynucleotide of SEQ ID NO:344. Applicants have not provided any guidance as to what critical residues, or bases, are required to maintain the functional characteristics (e.g. chondrocyte proliferation) of the polypeptide of SEQ ID NO:345, or of the encoding polynucleotide of SEQ ID NO:344, respectively, nor is it predictable to one of ordinary skill in the art how to make a functional polypeptide, or encoding polynucleotide, which is less than 100% identical to that of SEQ ID NO:345 or 344, respectively.

In summary, the breadth of the claims remains excessive with regard to Applicants claiming all polynucleotides which are less-than the full length of SEQ ID NO:344 and which encode polypeptides which are less than the full length of SEQ ID NO:345. There is also a lack of guidance and working examples of these polynucleotides and encoded polypeptides as well as which bases and residues are critical for polynucleotide and polypeptide function. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a functional polypeptide other that that of SEQ ID NO:345, or encoding polynucleotide of SEQ ID NO:344, leads the Examiner to maintain that undue experimentation is necessary to practice the invention as claimed. It is believed that all pertinent arguments have been addressed.

C. No rejection is being made over claim 137 even though it does not recite that the host cell is "isolated." When read in light of the specification, these claims do not read on gene therapy. As defined in the specification "host cells are transfected or transformed with expression or cloning vectors described herein for PRO production *and cultured in conventional nutrient media* modified as appropriate for inducing promoters, selecting transformants, or amplifying the genes encoding the desired sequences" (emphasis added). The fact that these cells are cultured in conventional media demonstrates that these host cells are not transgenic.

6. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claims 119-126, 129-131 and 135-138 under 35 USC 112, first paragraph, has been withdrawn in view of Applicants' amendments to the claims to include a functional limitation. However, claims 132 and 134 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action mailed 5/6/04. Applicants have not included any functional limitations in the claim.

7. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 119-126, 129-132 and 134-138 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims to delete reference to the "extracellular domain."

B. The rejection of claims 132 and 134 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendments to the claims to provide exact hybridization conditions.

8. Claim Rejections - 35 USC § 102

A. The rejection of claims 119-126, 129-132 and 134-138 under 35 USC 102(b) has been withdrawn in view of Applicants' arguments. The rejection should have been made under 35 USC 102(e).

B. Claims 132 and 134 are rejected under 35 USC 102(e) as being anticipated by Ni et al. (U.S. Patent 6,566,498 - see Form PTO-892 mailed 5/6/04). The claims recite a polynucleotide which hybridize to SEQ ID NO:344, or one encoding SEQ ID NO:345. Ni teach a polynucleotide which is 51% identical to SEQ ID NO:344 and which encodes the polypeptide which is 89% identical to SEQ ID NO:345. This nucleic acid molecule will hybridize to that of the present invention even under the most stringent conditions.

9. Conclusion

A. Claims 124-126, 129-131, 135-138 are allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
September 13, 2004